DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 8, 2014

Syneron Medical Ltd.
c/o Ms. Janice Hogan
Hogan Lovells US LLP
1835 Market Street, 29th Floor
Philadelphia, PA 19103

Re: K141507
Trade/Device Name: eTwo Skin Treatment System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical, Cutting & Coagulation & Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 4, 2014
Received: November 4, 2014

Dear Ms. Hogan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*

K141507

Device Name

eTwo Skin Treatment System

Indications for Use *(Describe)*

The eTwo Skin Treatment System is intended for dermatological procedures.

The Sublative RF applicator is indicated for dermatological procedures requiring ablation and resurfacing of the skin, and for the treatment of facial wrinkles. At higher energy levels greater than 62 mJ/pin, the Sublative RF applicator is limited to skin types I-IV.

The Sublime applicator is indicated for non-invasive wrinkles treatment. At higher energy levels greater than 100 J/cm^3, the Sublime applicator is limited to skin types I-IV.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) SUMMARY
Syneron Medical Ltd.'s eTwo Skin Treatment System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Syneron Medical Ltd.
P.O.B 550 Industrial Zone
Tavor Building,
Yokneam Illit 20692, Israel

Tel: +972 (0) 732-442-200
Fax: +972 (0) 732-442-202

Contact Person: Ruthie Amir, MD, Global Vice President of Clinical and Regulatory Affairs

Date Prepared: December 5, 2014

Name of Device

eTwo Skin Treatment System

Common or Usual Name

Electrosurgical cutting and coagulation device and accessories

Classification Name/Product Code

Classification: 21 CFR 878.4400, Electrosurgical cutting and coagulation device and accessories
Product Codes: GEI (Electrosurgical, cutting & coagulation & accessories), OUH (Skin resurfacing RF applicator)

Predicate Devices

Syneron eTwo Skin Treatment System (K110672)
EndyMed Medical, Ltd.'s Glow (K120513, K083461, K101510)

Intended Use / Indications for Use

The eTwo Skin Treatment System is intended for dermatological procedures.

The Sublative RF applicator is indicated for dermatological procedures requiring ablation and resurfacing of the skin, and for the treatment of facial wrinkles. At higher energy levels greater than 62 mJ/pin, the Sublative RF applicator is limited to skin types I-IV.

The Sublime applicator is indicated for non-invasive wrinkles treatment. At higher energy levels greater than 100 J/cm^3, the Sublime applicator is limited to skin types I-IV.

Device Description

The eTwo Skin Treatment System is a mobile system combining two existing technologies and applications for dermatological procedures.

The Sublative RF applicator delivers bipolar radiofrequency (RF) to the skin surface via an array of multi-electrode pin tips. The applicator delivers bipolar RF energy to the skin, which results in heating of demarcated spots of skin to temperatures that result in ablation and resurfacing of the skin that comes in contact with the multi-electrode pins.

The Sublime applicator uses a combination of an infrared (IR) light source and bipolar radiofrequency (RF) to bulk heat the dermis and affect dermal collagen in order to treat wrinkles. The bulk heating of the dermal layers refers to the gradual and gentle accumulation of heat with each additional pass performed.

Technological Characteristics

The eTwo System has generally the same technological characteristics as cleared in the predicate eTwo System, including device design, material, and energy source, except the subject eTwo System includes an additional 44-pin electrode tip and allows for higher RF energy levels to be delivered. The Sublime applicators of the eTwo Systems provide IR light and RF energy to the treatment area, whereas the non-ablative applicator of the EndyMed predicate provides RF energy only. The ablative applicators of the eTwo System and its predicates deliver RF energy to the treatment area. The hardware of the subject eTwo remains the same as previously cleared in the prior iteration of the device system.

Performance Data

Software

Software verification and validation was performed to evaluate the minor software changes made to support the increase in RF energy for the Sublime and Sublative RF applicators and to support the additional tip configuration (44 pin). Results showed that the Sublime and Sublative RF applicators with the eTwo Skin Treatment System function as intended.

Electrical Safety and Electromagnetic Compatibility

The eTwo System has been evaluated for electromagnetic compatibility and electrical safety testing per applicable standards of IEC 60601-1-2 and 60601-1, and all results were passing.

Histological Evaluations

Histological evaluation of skin tissues treated with the Sublime and Sublative applicators examined the impact of each applicator on skin tissue under the treated area, and demonstrated that the device performs as intended.

Sterilization Validation

Sterilization validation study results demonstrated that the sterilization method for the eTwo System continues to provide a minimum sterility assurance level of 10^{-6}, including for the additional 44-pin tip.

Clinical Study

In addition, the eTwo System treatment was evaluated in a prospective multi-center clinical study of 72 subjects through 24 weeks of follow up after the end of treatment. Four follow up visits (1 week, 6 weeks, 12 weeks, and 24 weeks after treatment) were scheduled for subjects receiving 1 treatment session, and five follow up visits (1 week, 6 weeks, 12 weeks, 18 weeks, and 30 weeks after first treatment) were scheduled for subjects receiving 2 treatment sessions. The study evaluated the higher energy levels and the additional 44-pin tip of the subject eTwo System through assessments by blinded evaluators, investigators, and subjects. Subjects' results at each follow up visit were compared to baseline to determine the amount of improvement with treatment. The primary endpoint of the study was to evaluate the reduction in wrinkles in the treated areas at 12 weeks following the last treatment session compared to baseline, based on photographic assessments by three independent blinded evaluators using the Fitzpatrick Wrinkle and Elastosis Scale (Degree of Elastosis categorized from class I (mild) to class III (severe)). The study also evaluated the safety of the treatment and recorded the number and type of any adverse event during the study. Additional assessments included the Global Aesthetic Improvement scale and patient satisfaction.

The majority of the enrolled population was female, Caucasian, with Fitzpatrick skin type II or III. Mean age was 49 years. The study population presented to the study with a range in Fitzpatrick Wrinkle and Elastosis scores and skin quality.

The pivotal study of the eTwo System demonstrated that device treatment achieves wrinkle reduction under the proposed parameters for a majority (71%) of the study subjects, meeting the primary study endpoint for effectiveness (50%). Results of secondary endpoint analyses showed improvement in wrinkles as observed in blinded evaluation, by investigators, and as perceived by subjects themselves over time. At the primary endpoint visit (12 weeks post treatment end), investigator assessments determined that 77% of the subjects were rated as improved from baseline (i.e., at least 1 unit improvement in Fitzpatrick Scale) and 91% of the subjects showed an overall improvement in facial appearance, further confirming the favorable results reported in

blinded evaluation. In addition, high levels of patient satisfaction were reported by the subjects, where the majority of subjects (≥63%) reported being satisfied or very satisfied with treatment throughout follow up. Treatment-associated discomfort or pain immediately following treatment generally resolved within a week.

At the proposed higher RF energy levels and with the additional 44-pin tip, the eTwo treatment continued to demonstrate a favorable safety profile with 6.9% (5/72 subjects) device-related adverse events throughout the study. All of the device-related adverse events were mild to moderate, and each event completely resolved during the study (most resolved within a few hours or days). There were no severe or serious adverse events in the study and no subjects discontinued from the study due to adverse events. A few subjects reported hyperpigmentation or hypopigmentation following treatment, which were also recognized as treatment-associated responses. In total, 11 subjects reported any changes in pigmentation or texture. Of these subjects, the events resolved for 6 subjects (most within a few days). For the remaining 5 subjects, results showed that the noted event was not associated with a negative clinical impact on the patient. Therefore, the clinical study data demonstrate that the eTwo System performs as intended with a favorable safety and effectiveness profile.

Substantial Equivalence

The eTwo System has the same intended use as the predicate devices. The eTwo System indications for use are the same as the predicate eTwo device, and similar to those of the EndyMed Glow predicate. The eTwo System presents similar technological characteristics and principles of operation as the predicate devices. The key technological differences between the current and predicate eTwo Systems are in terms of the increased RF energy level and the addition of an electrode pin tip size. The proposed eTwo treatment parameters have been evaluated in clinical testing, and results demonstrate that the device continues to perform as intended. The EndyMed predicate similarly presents higher levels of RF energy. Although the EndyMed device differs in terms of the energy type delivered (RF only) compared to the eTwo Systems (RF only and IR combined with RF), this difference does not raise new types of safety or effectiveness questions given that the predicate eTwo utilizes the same combination of energies. Further, the underlying mechanisms of all three devices are consistent to achieve the same intended therapeutic effect for wrinkles treatment. Therefore, the eTwo System has satisfied the criteria for substantial equivalence.

Conclusions

Syneron's eTwo System has been evaluated in nonclinical and clinical testing, and results demonstrated the device performance is appropriate for its intended use. The eTwo System presents the same intended use and similar indications for use, technological characteristics, and principles of operation as its predicate devices. Therefore, the eTwo System is substantially equivalent to the predicate devices.